Claims 2-3, 5 to 10 and 16 to 19 are finally rejected under 35 U.S.C. § 103 as being unpatentable over Harms, GB 2,034,731. The examiner asserts that the claimed compounds are rendered *prima facie* obvious by the teachings of Harms "absent a showing of criticality" since structurally similar compounds are generally expected to have similar properties. The examiner points out that the preferred bridge member of claims 8, 9 and 19 is specifically listed on line 35 of page 1. Applicants respectfully traverse this rejection.

Applicant acknowledges that the preferred bridge member of claims 8, 9 and 19 is specifically listed on line 35 of page 1 of Harms but does not appear in any of the disclosed dyes. Applicant avers that the dyes of Harms having the closest structural similarity to the instantly claimed dyestuffs are the dyes which are in principle obtainable from the reactants shown in Examples 48 and 74 of Harms. Accordingly, a proper comparison with the dyes of the prior art would have to be made with the dyes of said Examples. Said examples are based on the same C₅-diamine reactant, 2,4-diaminopentane.

Applicant has previously responded to the rejection over Harms by pointing out that the mere naming of a compound in a reference without more cannot constitute a description of a compound, particularly when the evidence of record suggests that no method exists for its preparation. See *in re Wiggins et al.*, 179 USPQ 421, 425 (CCPA, 1973). See also *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968).

It was pointed out that 2,4-diaminopentane is not commercially available, at least according to applicant's knowledge, and the reference is <u>absolutely silent</u> on how it is obtainable. Moreover, <u>no</u> significant properties are listed for the dyes of Examples 48 and 74. Further, from page 11, lines 28-30 and page 17, lines 27-28, it appears that Examples 48 and 74 (as well as the other dyes obtainable from the indicated reactants), are merely prophetic.

A declaration was furnished which established that 2,4-diaminopentane, the C₅-diamine needed to obtain the dyes shown in prophetic Examples 48 and 74 of Harms, could not be made by procedures generally employed in the art of amine preparation. Responsive thereto the examiner stated that the validity of a patent cannot be questioned.

Applicant avers that the statement that the validity of a patent cannot be questioned is incorrect in fact and law. Patents may not only be questioned; they can be and in many cases <u>are invalidated</u>, either in litigation or by the PTO during interference, reissue, reexamination and public use proceedings.

According to the <u>Manual of Patent Examining Procedure</u> (MPEP), § 2121 a reference is <u>presumed</u> to be operable. The burden then shifts to the applicant to provide facts rebutting the presumption of operability. See *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

MPEP § 2121 further points out that it does not matter whether the prior art reference is a U.S. patent, a foreign patent a printed publication or other. The level of disclosure required to make reference an "enabling disclosure" is the same. There is no basis in the statute (35 U.S.C. 102 or 103) for discriminating either in favor of or against prior art references on the basis of nationality.

MPEP § 2121.01 states that a reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention". *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

As set forth in MPEP § 2121.02, "a reference is presumed operable until applicant provides facts rebutting the presumption of operatibility. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention".

"When a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1971)".

Applicant also directs the examiner's attention to the <u>Guidelines for the Examination of Claims</u>

<u>Directed to Species of Chemical Compositions Based Upon a Single Prior Art Reference</u>, published by Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks in September of 1998. Its summary states

The Patent and Trademark Office (PTO) is publishing the final version of guidelines to be used by Office personnel in reviewing a certain type of patent application for compliance with 35 U.S.C. 103. The guidelines are to be used when examining claims directed to a species or subgenus of chemical compositions when: (1) the claims have been rejected based upon a single prior art reference, and (2) the single prior art reference discloses a genus embracing the claimed species or subgenus but does not expressly describe the particular claimed species or subgenus.

According to footnote 55 therein, the court in In re Hoeksema stated:

"Thus, upon careful reconsideration it is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. [footnote omitted.] In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds."

The *Hoeksema* court further noted that once a prima facie case of obviousness is made by the PTO through citation of references, the burden is on the applicant to produce contrary evidence establishing that the reference being relied on would not enable a skilled artisan to produce the different compounds claimed. Id. at 274-75, 158 USPQ at 601. See also *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 295, 297, 227 USPQ 657, 666, 667 (Fed. Cir. 1985) (citing *Hoeksema* for the proposition above); *In re Grose*, 592 F.2d 1161, 1168, 201 USPQ 57, 63-64 (CCPA 1979) ("One of the assumptions underlying a prima facie obviousness rejection based upon a structural relationship between compounds, such as adjacent homologs, is that a method disclosed for producing one would provide those skilled in the art with a method for producing the other. * *** Failure of the prior art to disclose or render obvious a method for making any composition of matter, whether a compound or a mixture of compounds like a zeolite, precludes a conclusion that the composition would have been obvious.")

Applicant avers that he has met the burden of proof set forth in the court decisions referenced above. As stated in *In re Wiggins*, "evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability" [emphasis added]. Applicant's objective evidence that 2,4-diaminopentane, the C₅-diamine needed to obtain the

dyes shown in prophetic Examples 48 and 74 of Harms, cannot be made by procedures generally employed in the art of amine preparation, stands unrebutted by the examiner.

Once more, since the dyes of Example 48 and 74 cannot be considered as prior art against the subject matter of independent claim 16, applicant respectfully requests the examiner to reconsider the comparison submitted in applicant's earlier declaration dated August 22, 1996, wherein the dye of Example 78 of Harms et al. was compared to a claimed dye. The dyestuffs A and X in said declaration differed from each other only with respect to the diamino bridge member. The prior art dye of Example 78 is based on a diamine which contains <u>four</u> carbon atoms. The declaration clearly showed that dye A according to the present application had a distinctly better affinity to cotton fiber material. The expert found the extent of the improvement to be very surprising and unexpected in view of the structural similarity of the compounds, and to be of considerable practical and commercial importance.

Reconsideration and withdrawal of the rejection of claims 2-3, 5 to 10 and 16 to 19 under 35 U.S.C. § 103 as being unpatentable over Harms, GB 2,034,731 is respectfully solicited in light of the remarks *supra*.

Since there are no other grounds of objection or rejection, passage of this application to issue with claims 2-3, 5 to 12 and 16 to 19 is earnestly solicited.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the Examiner contact the undersigned representative.

Respectfully submitted,

evin T. Manefield

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